OPTN Kidney & Pancreas Continuous Distribution Review Boards Workgroup
Meeting Summary
September 27, 2022
Conference Call

Asif Sharfuddin, MD, Chair

Introduction

The Kidney & Pancreas Continuous Distribution Review Boards Workgroup (the Workgroup) met via Citrix GoTo teleconference on 09/27/2022 to discuss the following agenda items:

1. Welcome and Refresher
2. Exceptions Discussion
3. Closing Remarks

The following is a summary of the Workgroup's discussions.

1. Welcome

The Chair welcomed the Workgroup to the meeting, and then asked Workgroup members attending their first meeting to introduce themselves. The Chair then provided a brief refresher on the purpose of the Workgroup. The Workgroup will:

- Establish a framework for review boards for kidney and pancreas, the Workgroup's
- Develop/provide recommendations to the OPTN Kidney Transplantation Committee and the OPTN Pancreas Transplantation Committee for their approval to be incorporated into the August 2023 continuous distribution proposal.

The staff reviewed the timeline for the Workgroup with January 2023 being the target date for recommendations to be sent to the proper committees.

Summary of discussion:

No discussion

2. Exceptions Discussion

Staff reviewed several attributes for the purpose of identifying possible exceptions for the review board to consider within the context of continuous distribution.

Presentation summary:

Exceptions are attribute-based, candidate specific and known prior to the time of the match run. The attributes being considered have previously identified by the OPTN Kidney and Pancreas Committees in the development of the continuous distribution project. Attribute-based exceptions are more tangible, consistent, and flexible. Exceptions are to shift a candidate's position on the rating scale and grant a candidate more points for that specific attribute. Exceptions do not change the weight of the attribute nor the importance of that attribute relative to other attributes. Donor factors are also attribute based. Goals are less tangible, less objective and consistent, and less flexible in programming. Staff provided a generic visual example of an adjusted non-linear and non-binary rating scale.

Staff provided some feedback from the OPTN Lung Transplantation Committee during their development of continuous distribution:

- Identify pain points in the current system
- Areas where patients are not well represented.
- Determine what aspects could be considered more straightforward and common exceptions
- Consider exceptions could be granted at an attribute level

The Workgroup needs to determine which attributes might a candidate's score not accurately reflect their needs. For example, currently for kidney waiting time, programs submit a waiting time modification form justifying why the waiting time modification is necessary. If approved, the candidate's waiting time can be modified. Placement efficiency would not be appropriate to grant an exception because this attribute is calculated at the time of the match run.

Staff provided a brief review of certain attributes before discussion.

Kidney Attributes: Medical Urgency:

- The attribute is on a binary rating scale
- This attribute is defined in *OPTN Policy 8.5.A.1*
- To qualify for medically urgent status the candidate must be
    - An active candidate
    - Accruing waiting time, according to *OPTN Policy 8.4*
- The candidate must be certified by a transplant nephrologist and transplant surgeon as medically urgent based on the following criteria:
    - First, the candidate must have exhausted, or has a contraindication to, all dialysis access via all of the following methods:
        - Vascular access in the upper left, upper right, lower left, and lower right extremities
        - Peritoneal access in the abdomen
    - After exhaustion or contraindication to all dialysis via the methods listed above, the candidate must also either have exhausted dialysis, be currently dialyzed, or have a contraindication to dialysis via one of the following methods:
        - Transhepatic IVC Catheter
        - Translumbar IVC Catheter
        - Other method of dialysis (must specify)

Staff noted that currently, programs list a candidate at medically urgent status and submit supporting documentation explaining the candidate's loss of dialysis access. The documentation is reviewed by the Kidney Medical Urgency Review Subcommittee. Currently, pancreas does not have a definition for medical urgency, but the OPTN Pancreas Committee is considering what that definition and criteria could be to incorporate into a future iteration of the project

Kidney Attributes: DR-Matching:

- Rating Scale: 0, 1, or 2 mismatches between the candidate and the donor
- Level of DR mismatch is not known before time of match run, programs could not submit an exception request for a candidate based on level of DR matching
- Since this is not known prior to time of match run, DR Matching would not qualify as an exception

Kidney Attributes: Longevity Matching:

Longevity matching involves matching between a candidate's Estimated Post-Transplant Survival (EPTS) score and the donor's Kidney Donor Profile Index (KDPI). The EPTS of the candidate is known prior to the match run. Each candidate 18 years or older on the kidney waiting list receives an EPTS score, which represents the percentage of kidney the candidates in the nation with a longer expected post-transplant survival time. All pediatric candidates will be assigned an EPTS score of 1, as the Pediatric Committee's data request shows that EPTD is not validated for pediatric candidates.

EPTS is based on:

- Candidate years on dialysis
- Whether or not the candidate has a current diagnosis of diabetes
- Whether or not the candidate has had any prior solid organ transplant
- Candidate age

Each candidate's EPTS score is updated any time the transplant hospital reports changes to any EPTS factor. Otherwise scores are updated daily. EPTS is on a continuous rating scale independent of KDPI. This expands longevity matching across the full spectrum of KDPI and EPTS.

Summary of discussion:

A member of the Workgroup stated they felt having the review board evaluate medical urgency for kidney cases makes sense. Pointing out that doing so would standardize the process making it difficult to game the system. The Chair agreed that this could, and should, be part of the review board's duties and it should not cause any delay in the process.

Another member of the Workgroup asked if allowing the review board to evaluate medically urgent requests would mean eliminating the subcommittee that currently handles those cases. The member also asked if the review board approve the cases prospectively rather than retrospectively. Staff answered that the review board would replace the subcommittee and the cases would be prospective rather than retrospective. The Workgroup member responded that it would be a good practice to establish and standardize.

The Chair stated that by standardizing the process for medical urgency, it would eliminate weaknesses that are currently seen in some of the documentations submitted by programs. The Chair voiced support in the review board taking on this responsibility, and asked the Workgroup of any negative impacts. No Workgroup members were able to name a negative impact.

A Workgroup member had a logistical question regarding the timeframe for review. Another Workgroup member, who currently sits on a review board, responded that review boards have five days from the time they receive the case in their inbox to respond; if no response is received within the five days the case is automatically assigned to another review board member. A Workgroup member said that five days could be fatal for certain candidates. Staff responded that one proposal for review boards limits the time for response to three days before the reviewer is replaced. Staff continued that with some organs the shorter timeframe makes more sense. A Workgroup member asked if a case could be sent to more review board members and have the vote shutdown once the threshold for approval or denial is met in order to expedite the process.

A Workgroup member stated they believe the review board would be the appropriate process for reviewing medical urgency cases, especially for pediatric cases.

Staff noted there seems to be a consensus for allowing the review board to consider medical urgency cases. They noted that the comments regarding the timeframe discussion was recorded and would be considered as the process moves forward.

The Chair asked the Workgroup if any of them had come across a medically urgent case that was not related to vascular access. One Workgroup member stated that most of those patients would not be listed as a transplant candidate until their situation improves. The Chair then asked about patients with a variety of side effects and the way the review board could handle those cases, a Workgroup member responded that considering each specific side effect could be subjective and may overwhelm the review board. Another Workgroup member said that in certain pediatric cases this may be a necessary review. The Chair responded that pediatrics will be discussed in a later meeting, Staff made note of the comment to bring up in a later meeting.

A Workgroup member stated they do not believe that DR matching would be appropriate for a review board to consider, and the Chair agreed.

Regarding longevity matching, the Chair stated their belief that a patient who has a graft failure post-transplant should be listed with their old EPTS rather than the new score following the failed transplant. This is particularly important to pediatric patients who need a second or third transplant later in life. The Chair asked if granting exceptions for certain age groups would be supported by other Workgroup members. A Workgroup member supported this idea. The Chair recommended waiting for modeling to come out before proceeding with this discussion.

A Workgroup member pointed out that older patients who receive high KDPI kidneys that fail are often sicker after transplant than before, these patients then must accept another high KDPI kidney. The Workgroup member felt this was not an equitable practice. Another Workgroup member said they agree and the recovery of high KDPI organs should be addressed. The Chair responded to the first Workgroup member by stating that this scenario could result in a number of candidates who have primary non-function bring negatively impacted by the fact they had a failed graft, and making their EPTS score worse. The Chair requested staff to make a note of this to bring back up in a future discussion and to find some data addressing this issue.

3. Closing Remarks

The Chair asked Workgroup members to consider some of the points that will be discussed ahead of time to allow the discussion to be more fruitful.

Summary of discussion:

Staff stated they would share the slides for the attributes earlier to allow the Workgroup to think about the topics more prior to their next meeting.

Upcoming Meeting

- October 11, 2022

Attendance

- **Workgroup Members**
  - Asif Sharfuddin
  - Dean Kim
  - Maria Friday
  - Elliot Grodstein
  - Michael Marvin
  - Raafat Qbeiwi Reem
  - Todd Pesavento
  - Antonio DiCarlo
- **HRSA Representatives**
  - First Name Last Name
- **SRTR Staff**
  - First Name Last Name
- **UNOS Staff**
  - Alex Carmack
  - Jennifer Musick
  - Joann White
  - Keighly Bradbrook
  - Lauren Motley
  - Lindsay Larkin
  - Sara Booker